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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,096	12/03/1998	DANIEL B. DRACHMAN	01107.77737	8208

7590 04/17/2002

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EXAMINER
SORBELLO, ELEANOR

ART UNIT	PAPER NUMBER
1632	21

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/205,096	DRACHMAN, DANIEL B:	
	Examiner	Art Unit	
	Eleanor Sorbello	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *15 December 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *NONE*.

Claim(s) objected to: *NONE*.

Claim(s) rejected: *41-67*.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Deborah Reynolds

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Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the instant invention is directed to (1) an ex vivo method wherein APC cells are transfected with a nucleotide sequence that encodes all or a portion of the autoantigen to which the patient's antigen-specific T cells respond (claims 41-53, 65); (ii) Antigen-Presenting Cells of an auto-immune patient transfected with a nucelotide sequence encoding all or a portion of the auto-antigen (54-57, 66); (iii) virus which comprises a polynucleotide that encodes all or a portion of the auto-antigen (claims 58-64, 67).

Applicants argue that examiner contends that ex vivo gene therapy is not enabled across the board and that analogous experimentation is therefore required to support that which is not provided for in the prior art. Applicants argue that the declaration provides analagous experimentation wherein HA transgenic mice (that express an HA specific T cell receptor) are injected with APC cells transduced with HA, FL and trucated FADD. Applicants declaration indicated that the HA trasngenic mice had the least number of CD4+ T cells expressing the HA indicating that the transduced T cells were ablated. Applicants base claim however is directed to a method of ablating T cells by administering transduced APC cells which cause the T cells in the autoimmune patient to be activated, and the pratictioner is required to subsequently administer a product that is detrimental to activated T cells. It is also not clear to the examiner if one if skill in the art would actually want to activate T cells in an autoimmune patient which may exacerbate an already existing severe condition rather than decrease the symptoms of the condition. Further it is not clear that the HA transgenic mouse is an art accepted model for MG, because it is known that the T cell response to the autoantigens in MG is highly heterogenous. Additionally, is this transgenic mouse having an HA specific T cell receptor representative of any autoimmune disease?

Applicants claims encompass a virus for the intended use of being administered to an autoimmune patient. It is not clear to the examiner if all other segments of the viral vector are removed because it is clear that by administering a virus to a patient with an autoimmune disease having segments of the wild-type virus, will definitely exacerbate an already existing deficient immune system. Therefore as stated in the office action dated 7/13/01 in paragraph bridging pages 6 and 7 applicants are not enabled for administering a viral vector for the intended purpose of providing therapy to an autoimmine patient.

Applicants argue that the instant invention is directed to a method of ablating T cells which had been modified previously by a nucleotide encoding the autoantigen and then reintroduced into the individual and then another product such as Fas ligand or FADD is added. The narrower claims however recite that the Fas ligand or FADD is also expressed by the APC cells. Applicants argue that even if ex vivo therapy is not enabled, claims directed at the virus and APCs should be enabled. However, examiner argues that the virus and APCs of the instant invention have only one intended use of being used for ex vivo therapy to one individual with a specified autoimmune condition. Therefore, for the same reasons discussed herein and stated in the Office Action dated 7/13/01, the claims stand rejected.